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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/488,298	01/20/2000	Olivier Lutz	3874-128 US	4242

7590 07/28/2004

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/488,298	LUTZ ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 7-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/24/2004 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4 and 7-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "wherein not more than about 1.5% of said tocopherol is free tocopherol" lack literal support in the specification as filed. This is New Matter rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 4 and 7-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Lambert et al. (U.S.Patent No. 6,458,373B1) of record.

Lambert et al. teach a micelle solution or an emulsion with a particle size of 10 to 500 nm comprising chemotherapeutics including podophyllotoxins (etoposide) and their derivatives and analogues, tocopherol and TGPS (d-a-tocopherol polyethyleneglycol 1000 succinate). (abstract, column 3, lines 45-58, column 4, lines 1-3, column 7, lines 39-65, column 8, line 59, column 10, lines 28-33, column 21, Example 23).

Lambert et al. teach use of Applicants' water-soluble polymer, polyoxypropylene-polyoxyethylene copoymer in the above composition. (column 3, lines 59-64).

Lambert et al. teach use any compound including peptides, lipid conjugates/prodrugs, and any natural or synthetic molecule which are slightly or completely lipophilic, and any molecules which stimulate the immune system in the above composition. (column 6, lines 54-56).

Lambert et al. teach the amounts of TPGS about 10% in the above composition. (column 21, Example 23).

Lambert et al. teach the concentration of free a-tocopherol in the solution is less than 1.0%, generally less than 0.5%. (column 22, lines 50-60).

Lambert et al. teach that above composition can be administered to treat melanoma tumors in nude mice. (Example 18, table 2).

Applicants' recitation of tocoferol covalently linked to a water-soluble polymer does not represent a patentable limitation since such fails to impart any physical limitation to the composition and it would be inherent in the same composition taught by prior art constituted with same active agents, same formulation (micelle, emulsion), same particle size with same amount of "not more than about 1.5%" (1.0%) of free tocopherol.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 102(e).

None of the claims are allowed.

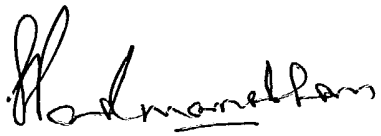
Response to Arguments

Applicants' arguments filed May 24, 2004 have been fully considered but they are not persuasive. Applicants argue the formulations contemplated by Lambert et al. all require calculated an intentional additional free tocopherol as a substantial and critical element of the formulation per se, for the express purpose of solubilizing drug compounds, in addition to any tocopherol otherwise unavoidably present. This is not persuasive because Lambert et al. teach free a-tocopherol less than 1.0% which reads on Applicants' claimed limitation of less than about 1.5% of free-tocopherol as claimed by Applicants. It is also noted that the limitation "wherein not more than about 1.5% of said tocpherol is free tocopherol" lack literal support in the specification as filed and therefore it is new matter since Applicants' fail to recite the purity of tocoferol to be employed. Applicants next argue the addition of alpha-tocopherol (free tocopherol) in the amounts taught by Lambert, et al. to formulations comprising Etoposide and TPGS unequivocally dramatically reduces the solubility of Etoposide and leads to phase separation unless special emulsification procedure is used as described in the Lambert et al. as shown in the evidence and side by side comparison presented in the Declaration executed by Dr. Valery Alakhov presented March 30, 2004. This is not persuasive because claimed invention comprises same active agent, same amounts of free a-tocopherol and they are drawn to same active agents, same particle size, same formulation and therefore it is not patentably distinguish over the composition taught by prior art. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited reference.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
July 20, 2004